

PANDORA-2 protocol; intervention study to improve the quality of life in patients with small (≤ 2 cm) pancreatic neuroendocrine tumors

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Introduction

- New treatment strategy for small (≤ 2 cm) non-functioning pancreatic neuroendocrine tumors (NF-pNET) from tumor resection to an active surveillance strategy.
- The PANDORA-study (2016), an active surveillance protocol with prospective data collection including clinical outcomes and quality of life (QoL).
- Excellent outcome: 89% without any tumor growth and 2/76 (3%) had tumor growth leading to a resection.
- However, QoL of patients was decreased at baseline and during follow-up. Furthermore, there was suboptimal adherence to the advised surveillance protocol.

Reflecting on the preliminary results of PANDORA, two important aspects became clear:

1. PANDORA was designed from a medical perspective, with an effort not to miss pNETs with malignant behavior. Therefore, the surveillance protocol in PANDORA was intense with frequent imaging.
2. PANDORA did not have measures to support patients during their intensive follow-up protocol, apart from the available care in DPCG hospitals.

Goal: Improve QoL for patients with small NF-pNET undergoing active surveillance by reducing the burden of the current active surveillance protocol and by introducing a supportive care intervention.

Methods

Multicenter, prospective intervention study.

Inclusion criteria:

- ≥ 18 years
- NF-pNET of 2 cm or smaller
- The diagnosis is made with both a Ga-68 DOTATATE PET-CT and a CT-scan or MRI-scan.

Exclusion criteria:

- High-grade dysplasia
- Tumor growth
- Syndromal origin
- Hormone overproduction
- Signs of lymph node metastasis or distant metastasis

Intervention: Seven moments of radiological imaging over 10 years, compared to 13 moments in the previous PANDORA-study. In the third year of this study, new patients will also be given a supportive care intervention. Thereby creating two intervention groups.

Control: Previous PANDORA-cohort.

Outcome: Quality of life through online questionnaires.

Surgical resection recommended if:

- Patient develops symptoms
- Tumor is > 2 cm
- Tumor growth > 0.5 cm/year
- Pancreatic duct or common bile duct dilation
- Pathological lymph node enlargement
- Vascular involvement or infiltration of surrounding organs
- Patient expresses strong preference for surgical treatment

Results

Expected:

- Insights in the causes of the decreased QoL of PANDORA-patients
- Improving QoL while maintaining tumor control
- Implement a supportive care intervention
- Effect of this regimen on the adherence to the follow-up protocol
- A cost-benefit analysis

The life expectancy of this rare disease is almost unchanged and should therefore be with the best QoL. This study will be dedicated to that goal.

Low frequency follow-up protocol

1st year	3 months	EUS-FNB
	12 months	MRI/CT
3rd year	36 months	MRI/CT
5th year	60 months	MRI/CT
7th year	84 months	MRI/CT
10th year	120 months	MRI/CT